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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/674,172	01/04/00	BOHLE	A 10890-2MIS:J

EXAMINER	
ZEMAN, R	
ART UNIT	PAPER NUMBER
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DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/674,172	Bohle et al.
Examiner	**Art Unit**
Robert A. Zeman	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 4, 2000*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: Said claim contains an obvious grammatical error. The term "include" should read "includes". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-12, 16-18 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of **Bacillus Calmette-Guerin (BCG)** for the therapeutic treatment of condylomata acuminata, does not reasonably provide enablement for the use of **all** *Mycobacterium* species/strains for the therapeutic treatment of **all** disease conditions caused by papilloma virus infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. People of skill in the art require documented factual evidence, that a benefit can be derived by the therapeutic application of a substance. The specification provides ample factual evidence that BCG can be used to treat condylomata acuminata which is associated with papilloma virus infection. However, the instant

specification fails to provide direction on what *Mycobacterium* species/strains, other than BCG, are capable of eliciting a therapeutic response or that a given response would be beneficial to the treated subject. Applicant has failed give direction on what *Mycobacterium* species/strains, other than BCG, would meet the limitations of the claims and has provided no evidence that any benefit to the treated subject would be obtained. Human papilloma virus is associated with a myriad of human "disease conditions" including: verruca plantaris, verruca vulgaris, verruca plana, epidermodysplasia verruciformis (benign and squamous cell carcinoma), condyloma acuminatum, laryngeal papilloma, Butcher's warts, focal epithelial hyperplasia, cervical intraepithelial neoplasia, cervical carcinoma, oral papilloma, flat warts, macular lesions, Bowen's disease, bladder carcinomas and bladder papillomas. Applicant has not taught how to use BCG, or any other mycobacterium, to treat any of the aforementioned disease conditions. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of a therapeutic response in a living organism, the specification, as filed, is not enabling for the use of **all** *Mycobacterium* species/strains as a therapeutic treatment for any and all disease conditions caused by papilloma virus infections.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The methods of claims 1-15 are vague and indefinite as they are lacking in positive active steps of the methods. Method claims should contain all of the steps necessary for carrying out the invention. Said claims merely recite the limitations of the compound to be used in said method and do not point out necessary features of the method or components of the method.

Claims 1 and 16 are rendered vague and indefinite by the use of the term "region of infection". It is unclear what Applicant is referring to. Is the "region of infection" the site of papilloma virus infection or some other infection facilitated by the papilloma virus infection? Additionally, the use of the term "effective" renders claim 1 vague and indefinite. It is unclear to what purpose the composition is to be effective. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 5 and 17 are rendered vague and indefinite by the use of the term "tuberculosis complex". It is unclear what is meant by this term. Does the claimed *Mycobacterium* have to be part of a complex or merely have the ability to form such a complex? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 8 is rendered vague and indefinite by the confusing language used in reciting the multiple ranges that encompass the limitations of the claim. The aforementioned claims should be rewritten so that there is a clear demarcation of each limitation.

Claims 15 and 22 are rendered vague and indefinite by the use of the term "1 to about 10 wt.%". It is unclear what is being weighed. Is Applicant referring to a percentage of total composition? A component of the composition? As written, it is impossible to determine the metes and bounds of the claimed invention.

Regarding claim 24, the phrase "particularly" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 25, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 24 and 25 provide for the use of a therapeutic composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 24-25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 9 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Herr et al. (Journal of Urology Vol. 141, pages 22-29, 1989).

The instant invention is drawn to methods of treating disease conditions (warts papillomas, carcinomas etc.) caused by the papilloma virus. Said method comprises the application of a composition comprising a *Mycobacterium* (bacillus Calmette-Guerin). The recited methods of use also recite the use of said composition use as a topical cream whose use is preceded by ablative surgery of the region of infection (i.e. removal of papilloma etc.).

Herr et al. disclose a method of treating superficial bladder carcinomas and papillomas caused by human papilloma virus (HPV) with bacillus Calmette-Guerin (BCG). Herr et al. also disclose that the BCG treatment can follow the resection of the tumor (see materials and methods section beginning on page 22). Said disclosure anticipates all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herr et al. (Journal of Urology Vol. 141, pages 22-29, 1989) in view of Morton (GB2179858A)

The instant invention is drawn to a composition for treating disease conditions (warts etc.) caused by the papilloma virus and methods of using a composition comprising a *Mycobacterium* (bacillus Calmette-Guerin) and a keratolytic agent (salicylic acid). The recited methods of use of

said composition include its use as a topical cream whose use is preceded by ablative surgery (laser) of the region of infection (i.e. removal of papilloma etc.).

Herr et al. disclose a method of treating superficial bladder carcinomas and papillomas caused by human papilloma virus (HPV) with bacillus Calmette-Guerin (BCG). Herr et al. also disclose that the BCG treatment can follow the resection of the tumor (see materials and methods section beginning on page 22). Herr et al. differs from the instant invention in that it does not disclose the use of BCG to treat condylomata acuminata (genital warts) nor does it explicitly disclose the use of a laser to ablate the wart before the onset of treatment (said use is a common surgical practices and hence is obvious) or the use of salicylic acid as keratolytic agent in the treatment composition. Morton discloses the use of salicylic acid as a keratolytic agent in a topical compound that can be used to treat viral skin diseases including condylomata acuminata (see page 2 lines 15-17). Morton further discloses that the salicylic acid may comprise "up to 15% by weight" of the composition (see page 1, line 32). Finally, Morton discloses multiple composition forms for the topical application of the composition including a concentrated solution, a gel and an ointment. Since the use of creams/gels/ointments is commonly used to deliver a therapeutic composition to a treatment site it would have been obvious to one of skill of the art to use the BCG, as disclosed by Herr et al., in a salicylic acid-containing topical cream/gel/ointment as disclosed by Morton. in order to take advantage of the benefits of using a topical cream/gel (i.e. therapeutic composition adheres to area to be treated). One would expect the resulting composition to be an effective treatment for condylomata acuminata (warts) since BCG has been

demonstrated to be an effective treatment for papillomas, as disclosed by Herr et al.), which also has human papilloma virus as a causative agent.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

June 18, 2001